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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/566,611

01/31/2006

Gerhard Liepold

1350-3 PCT/US

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HOFFMANN & BARON, LLP  
6900 JERICHO TURNPIKE  
SYOSSET, NY 11791

EXAMINER

TIETJEN, MARINA ANNETTE

ART UNIT

PAPER NUMBER

3753

MAIL DATE

DELIVERY MODE

08/04/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/566,611	<b>Applicant(s)</b> LIEPOLD ET AL.	
	<b>Examiner</b> MARINA TIETJEN	<b>Art Unit</b> 3753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 50-90 is/are pending in the application.
- 4a) Of the above claim(s) 68-90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 50-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

1. This office action is responsive to the amendment filed on 04/17/2009. As directed by the amendment: claim 55 has been amended and claims 1-49 have been cancelled. Thus, claims 50-90 are presently pending in this application.

### ***Response to Arguments***

2. Applicants' arguments, see page 12-13, with respect to the rejection of claims 50-58 and 62-63 under Newberg (U.S. 6,491,283), filed 04/17/2009 have been fully considered but they are not persuasive.

Regarding the Applicants' argument that Newberg's valve teaches away from a sharp rim on a portion of the valve, even though Newberg discloses it is preferred for there not to be sharp edges on the valve internal passage, Newberg's valve is still capable of functioning with sharp edges and therefore does not teach away.

Furthermore, Newberg specifically discloses the Figs. illustrate sharp corners (col. 5, lines 65-66), despite rounded edges being preferred, and therefore Newberg discloses a sharp rim. Moreover, Newberg suggests the internal passages to have rounded corners, not the entry to the internal passage, which is where the Examiner referred to as the sharp rim being present.

Regarding the Applicants' argument that Newberg does not disclose deformation of the curved surface area upon engagement and that the two portions become elastically deformed, but instead discloses surface contact, deformation (even at a

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minute level) is deformation. Surface contact would at least cause deformation at a minute level. Any two things will deform when pushed together with enough force. Furthermore, the recitation "so that when the valve is in the closed position, the sharp rim engages the curved surface area and displaces a portion of the curved surface area thereby elastically deforming the materials of the sharp rim and the curved surface area to seal the opening of the valve" is a functional limitation of the structure. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

3. Applicants' arguments, see pg. 14, section B, filed 04/17/2009, with respect to the rejection(s) of claim(s) 50 and 59-65 under *Leipold* (WO 03/090842) in view of *Trumbower et al.* (U.S. Pat. No. 7,270,673) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of *Leipold* (WO 03090842) in view of *Rovira et al.* (U.S. Pub. No. 2002/0074532).

4. The instant Office Action has been made Non-Final.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

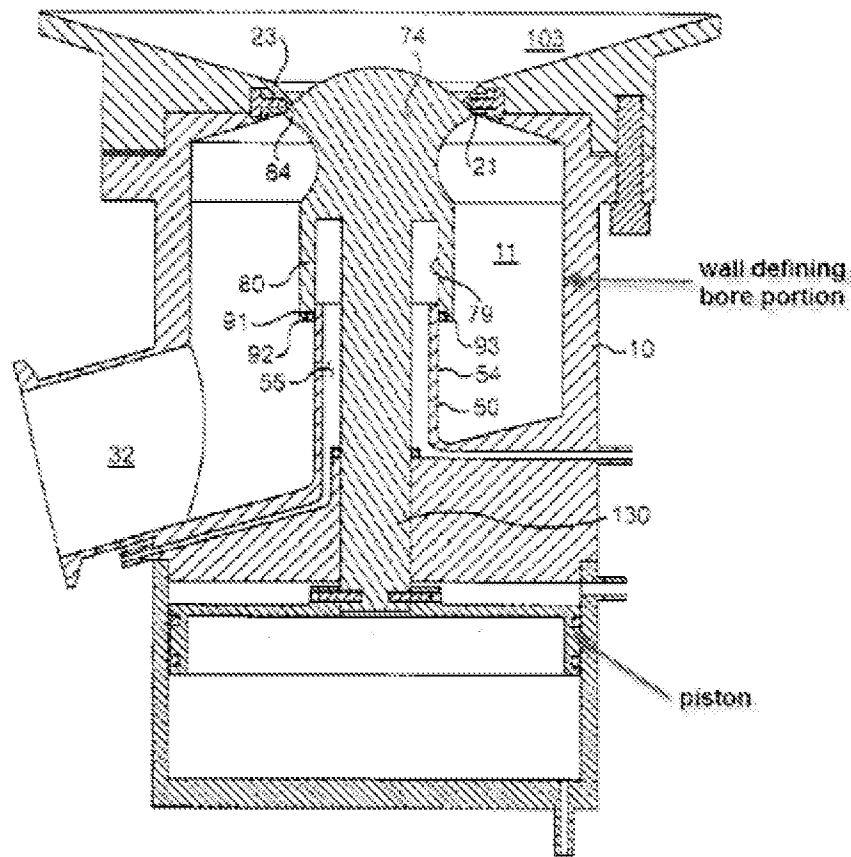
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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 50-58 and 62-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Newberg (U.S. Pat. No. 6,491,283).

Newberg discloses a valve (fig. 9) comprising a body (10, 100) having first (103) and second open (32) ends and a passageway (11) for fluid between the ends, the first end (103) including a first coupling means (105; fig. 1, col. 6, lines 30-36) for sealingly connecting the body (10, 100) about an opening (not shown, col. 6, lines 30-36) of a first external device (not shown) and a seal (21, 84) blocking an open area (20; fig. 1) of the first end (103), the valve further including a seal displacement means (74, 130, and piston in combination, see labeled Fig. 9 below) movable within the body so as to interrupt the seal (21, 84) permitting fluid to pass along the passageway (11) between the ends (103, 32), the coupling means (105) and the seal presenting a sterilisable mating surface for sealingly mating with a mating surface about the opening in the first external device (col. 6, lines 30-36), wherein the seal (21), (84) is formed between a first plastics portion (84) movable by the seal displacement means (74, 130) and a second plastics portion (21) disposed about the open area of the first end (103) of the valve;

wherein the second plastic portion (21) has a protruding sharp rim (fig. 9) and the first plastic portion (84) of the seal has a curved surface area (fig. 9) so that when the valve is in the closed position, the sharp rim (edge of 21) engages the curved surface area and displaces a portion of the curved surface area thereby elastically deforming the materials of the sharp rim and the curved surface area to seal the opening of the valve;



**FIG. 9**

wherein the engagement of the sharp rim (21) with the curved surface area occurs during a linear motion of the sharp rim (21) relative to the curved surface area;

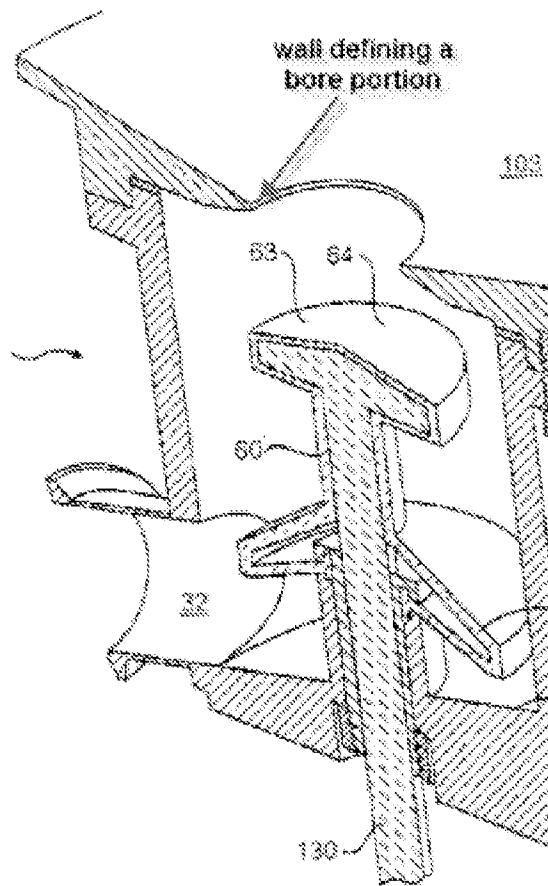
wherein the first plastic portion (84) is integrally formed (fig. 9) with the seal displacement means (74, 130);

wherein the first plastic portion (84) is provided by a plastic plug (74) integrally formed (fig. 9) with the seal displacement means (74,130);

wherein the second plastic portion (21) is integrally formed with the body of the valve (col. 15, lines 5-7);

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wherein the second plastic portion (21) comprises a wall defining a bore portion (see labeled fig. 9 above) having a cross-section converging towards the first end (103) of the valve which in turn leads to a wall defining a bore portion (best seen in labeled fig. 3 below) having a substantially uniform cross-section which is located adjacent the first end (103) of the valve, the boundary between the wall defining the converging bore portion and the wall defining the uniform bore portion defining the sharp rim (21), the first plastic portion (84) having a body portion (74) with a cross-section converging towards the first end (103) of the valve and leading to an end portion with a uniform cross-section, the end portion being adjacent the first end (103) of the valve in use and a transitional surface between the external surface of the body portion (100) and the external surface of the end portion of the first plastic portion (84) defining the curved surface area so that when the opening of the valve is sealed the sharp rim (21) engages the curved surface area and displaces a portion of the curved surface area thereby elastically deforming the materials of the sharp rim (21) and the curved surface area.



**FIG. 3**

wherein the curved surface area (of plug 74) has a predetermined radius (fig. 9);

wherein the second end (32) of the body (10, 100) comprises a second coupling means (34; fig. 1, col. 7, lines 20-22) with a mating surface for sealingly connecting the body about an opening of a second external device (not shown);

wherein the distance between the mating surfaces of the first (105) and the second (34) coupling means remains unchanged during movement of the seal displacement means (74, 130) within the body (10, 100) between open and closed positions of the valve;



wherein the body comprises a hollow housing (10; fig. 9) extending between the first (103) and the second open ends (32); and

wherein the seal displacement means comprises a piston (see labeled fig. 9 above) slidably movable within the housing, the piston having the first plastic portion (74) formed at the top end thereof.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

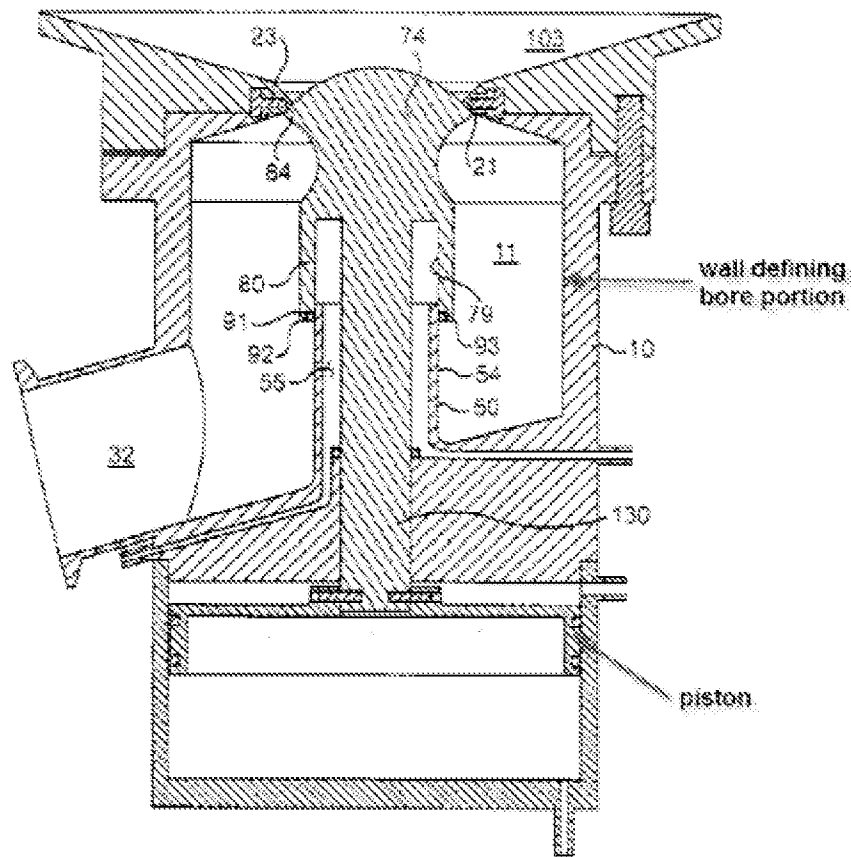
8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 61 and 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newberg (U.S. Pat. No. 6,491,283) in view of Jougla (U.S. Pat. No. 6,237,639).

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Newberg discloses a valve (fig. 9) comprising a body (10, 100) having first (103) and second open (32) ends and a passageway (11) for fluid between the ends, the first end (103) including a first coupling means (105; fig. 1, col. 6, lines 30-36) for sealingly connecting the body (10, 100) about an opening (not shown, col. 6, lines 30-36) of a first external device (not shown) and a seal (21, 84) blocking an open area (20; fig. 1) of the first end (103), the valve further including a seal displacement means (74, 130, and piston in combination, see labeled Fig. 9 below) movable within the body so as to interrupt the seal (21, 84) permitting fluid to pass along the passageway (11) between the ends (103, 32), the coupling means (105) and the seal presenting a sterilisable mating surface for sealingly mating with a mating surface about the opening in the first external device (col. 6, lines 30-36), wherein the seal (21), (84) is formed between a first plastics portion (84) movable by the seal displacement means (74, 130) and a second plastics portion (21) disposed about the open area of the first end (103) of the valve;

wherein the second plastic portion (21) has a protruding sharp rim (fig. 9) and the first plastic portion (84) of the seal has a curved surface area (fig. 9) so that when the valve is in the closed position, the sharp rim (of 21) engages the curved surface area and displaces a portion of the curved surface area thereby elastically deforming the materials of the sharp rim and the curved surface area to seal the opening of the valve;



**FIG. 9**

wherein the engagement of the sharp rim (21) with the curved surface area occurs during a linear motion of the sharp rim (21) relative to the curved surface area;

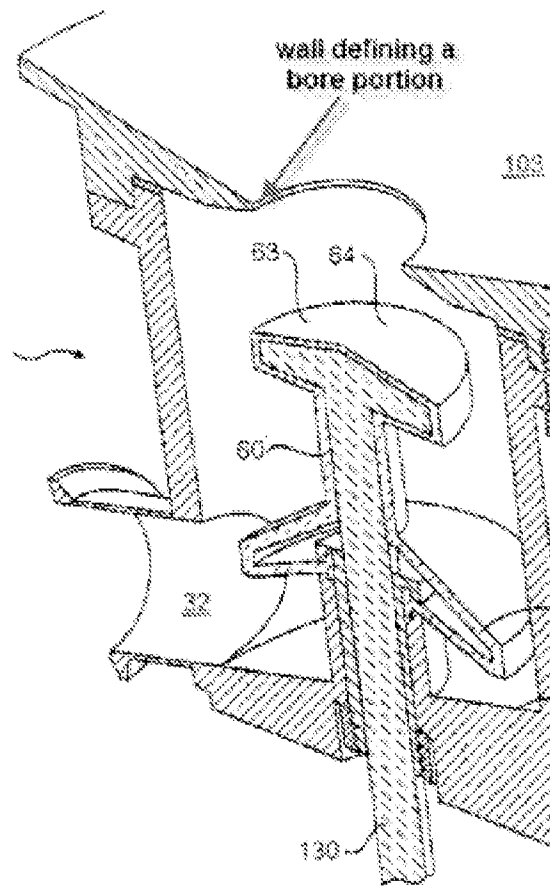
wherein the first plastic portion (84) is integrally formed (fig. 9) with the seal displacement means (74, 130);

wherein the first plastic portion (84) is provided by a plastic plug (74) integrally formed (fig. 9) with the seal displacement means (74,130);

wherein the second plastic portion (21) is integrally formed with the body of the valve (col. 15, lines 5-7);

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wherein the second plastic portion (21) comprises a wall defining a bore portion (see labeled fig. 9 above) having a cross-section converging towards the first end (103) of the valve which in turn leads to a wall defining a bore portion (best seen in labeled fig. 3 below) having a substantially uniform cross-section which is located adjacent the first end (103) of the valve, the boundary between the wall defining the converging bore portion and the wall defining the uniform bore portion defining the sharp rim (21), the first plastic portion (84) having a body portion (74) with a cross-section converging towards the first end (103) of the valve and leading to an end portion with a uniform cross-section, the end portion being adjacent the first end (103) of the valve in use and a transitional surface between the external surface of the body portion (100) and the external surface of the end portion of the first plastic portion (84) defining the curved surface area so that when the opening of the valve is sealed the sharp rim (21) engages the curved surface area and displaces a portion of the curved surface area thereby elastically deforming the materials of the sharp rim (21) and the curved surface area;



**FIG. 3**

wherein the curved surface area (of plug 74) has a predetermined radius (fig. 9);

wherein the second end (32) of the body (10, 100) comprises a second coupling means (34; fig. 1, col. 7, lines 20-22) with a mating surface for sealingly connecting the body about an opening of a second external device (not shown);

wherein the distance between the mating surfaces of the first (105) and the second (34) coupling means remains unchanged during movement of the seal displacement means (74, 130) within the body (10, 100) between open and closed positions of the valve;

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wherein the body comprises a hollow housing (10) extending between the first (103) and the second open ends (32); and

wherein the seal displacement means comprises a piston (see labeled fig. 9 above) slidably movable within the housing, the piston having the first plastic portion (74) formed at the top end thereof.

However, Newberg does not disclose means for displaying to a user the actuation state of the valve; an operating means having an actuator externally mounted on the body and movable between a first and a second end position, wherein the actuator is linked with the seal displacement means so that movement of the actuator between the first and the second end positions causes the seal displacement means to translate along the passageway between open and closed positions; wherein the actuator is linked with the seal displacement means via a cam pair; and at least one guide element provided in the valve to prevent rotational motion of the seal displacement means and to permit the seal displacement means to move only linearly in the passageway.

Jougla teaches an operating means (9) having an actuator (10) externally mounted on a body (1) and movable between a first and a second end position, the actuator (10) being linked with a seal displacement means (13) so that movement of the actuator (10) between the first and the second end positions causes the seal displacement means to translate along a passageway between open and closed positions, wherein the actuator (10) is linked with the seal displacement means (13) via a cam, wherein the actuator (10) position displays to the user the actuation state of the

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valve (based on the relative position of the actuator 10 to its overall stroke), and further teaches two guide elements (20) provided in the valve to prevent rotational motion of the seal displacement means (13) and to permit the seal displacement means (13) to move only linearly in the passageway for the purpose of providing a coupling and drive means that is simple in structure (col. 2, lines 16-17) yet ensures the reliability of the valve movement (col. 2, lines 51-56).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Newberg's invention to include an operating means having an actuator externally mounted on the body and movable between a first and a second end position, wherein the actuator is linked with the seal displacement means so that movement of the actuator between the first and the second end positions causes the seal displacement means to translate along the passageway between open and closed positions, wherein the actuator is linked with the seal displacement means via a cam pair, wherein the actuator position displays to the use the actuation state of the valve, and at least one guide element provided in the valve to prevent rotational motion of the seal displacement means and to permit the seal displacement means to move only linearly in the passageway, as taught by Jouglu, for the purpose of providing a coupling and drive means that is simple in structure yet ensures the reliability of the valve movement.

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10. Claims 50 and 59-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leipold et al. (WO 03/090842) in view of Rovira et al. (U.S. Pub. No. 2002/0074532).

Leipold et al. disclose a valve (100, fig. 1a) comprising a body (2) having first (2L) and second (2p) open ends and a passageway (fig. 1a) for fluid between the ends, the first end (2L) including a first coupling means (fig. 2a) for sealingly connecting the body (2) about an opening (4c) of a first external device (4) and a seal (2a) blocking an open area of the first end (2L) which in use is placeable in register with the opening (4c) of the external device (4), the valve further including a seal displacement means (1) movable within the body (2) so as to interrupt the seal (2a) permitting fluid to pass along the passageway between the ends, the coupling means and the seal (2a) presenting a sterilisable mating surface (12) for sealingly mating with a mating surface (13) about the opening (4c) in the first external device (4), wherein the seal (2a) is formed between a first plastics portion (1f, fig. 1i) movable by the seal displacement means (1) and a second plastics portion disposed (2b) about the open area of the first end of the valve (100);

wherein the seal displacement means (1) travels at least partially outside of the second end (2p) of the body (2) on actuation of the valve (100);

wherein the displacement means (1) comprise first (1f, fig. 1i) and second ends (110), the first end (1f) comprising the first plastic portion and the second end (110) comprising a coupling means for sealingly connecting the displacement means (1) about an opening of a second external device (not shown);



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wherein means (2r, fig. 1d) for displaying to a user the actuation state of the valve (100);

wherein the body (2) comprises a hollow housing (2i, fig. 1a) extending between the first (2L) and the second (2p) open ends;

wherein the seal displacement means (1) comprises a piston (fig. 1a) slidably movable within the housing (2), the piston having the first plastic portion (1f) formed at one end thereof;

wherein an operating means having an actuator (50, fig. 10b) externally mounted on the body (2) and movable between a first and a second end position, the actuator (50) being linked with the seal displacement means (1) so that movement of the actuator (50) between the first and the second end positions causes the seal displacement means (1) to translate along the passageway between open and closed positions; and

wherein the actuator (50) is linked with the seal displacement means (1) via a cam pair (50c, fig. 10b).

However, Leipold et al. fail to disclose one of the plastic portions has a protruding sharp rim and the other plastics portion of the seal has a curved surface area so that when the valve is in the closed position, the sharp rim engages the curved surface area and displaces a portion of the curved surface area thereby elastically deforming the materials of the sharp rim and the curved surface area to seal the opening of the valve.

Rovira et al. teach a valve member portion (2, fig. 2) has a protruding sharp rim (4, sharpness shown in figures is intended, para. 0044) and another plastics portion of a

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seal (3, plastic material disclosed in para. 0046) has a curved surface area (shown tapered but alternatively curved, para. 0042-0043) so that when the valve is in the closed position, the sharp rim (4) engages the curved surface area (3) and displaces a portion of the curved surface area thereby elastically deforming the materials of the sharp rim (4) and the curved surface area (3) to seal the opening of the valve, for the purpose of reducing misalignment of the valve member relative to the opening wherein the curved surface acts as a guide to center the valve member, and for providing superior sealing capabilities while allowing use of a lower force to actuate the valve (para. 0001).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Leipold's invention such that one of the plastic portions has a protruding sharp rim and the other plastics portion of the seal has a curved surface area so that when the valve is in the closed position, the sharp rim engages the curved surface area and displaces a portion of the curved surface area thereby elastically deforming the materials of the sharp rim and the curved surface area to seal the opening of the valve, as taught by Rovira et al., for the purpose of eliminating misalignment of the valve member relative to the opening, wherein the curved surface acts as a guide to center the valve member, and for providing superior sealing capabilities while allowing use of a lower force to actuate the valve.

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11. Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leipold et al. (WO 03/090842) in view of Rovira et al. (U.S. Pub. No. 20020074532) further in view of Astier (U.S. Pat. No. 1,387,446).

Leipold et al. in view of Rovira et al. disclose the invention as essentially claimed, except for a seal provided at both the first and the second open ends of the body, each seal having a seal displacement means movably disposed within the passageway of the body so that the first and/or second ends may be sealed or opened.

Astier teaches a seal (9, fig. 1) provided at both a first and second open ends (15) of a body (1), each seal (9) having a seal displacement means (6) movably disposed within the passageway (fig. 1) of the body (1) so that the first and second ends (15) may be sealed or opened for the purpose of ensuring tight closing of the apparatus since any escape of the fluid is successively opposed by the two sealed ends (col. 2, lines 82-85).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Leipold's invention in view of Rovira such that a seal is provided at both the first and the second open ends of the body, each seal having a seal displacement means movably disposed within the passageway of the body so that the first and/or second ends may be sealed or opened, as taught by Astier, for the purpose of ensuring tight closing of the apparatus since any escape of the fluid is successively opposed by the two sealed ends.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARINA TIETJEN whose telephone number is (571) 270-5422. The examiner can normally be reached on Mon-Thurs, 9:30AM-5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBIN EVANS can be reached on (571) 272-4777. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. T./  
Examiner, Art Unit 3753

/Robin O. Evans/  
Supervisory Patent Examiner, Art Unit 3753